UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE BRISTOL-MYERS SQUIBB SECURITIES LITIGATION	:	Civil Action No. 00-1990 (SRC)
	:	Return Date: June 6, 2005
	:	Oral Argument Requested

LEAD PLAINTIFF'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO STRIKE THE EXPERT TESTIMONY OF JONATHAN L. BENUMOF

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PRELIMINARY STATEMENT

Lead Plaintiff, the LongView Collective Investment Fund ("Lead Plaintiff"), respectfully submits this memorandum of law in opposition to defendants' motion to strike, pursuant to Rule 702 of the Federal Rules of Evidence, the testimony of Lead Plaintiff's airway management expert, Dr. Jonathan L. Benumof.[1] Defendant Bristol-Myers Squibb ("BMS" or the "Company"), along with individual defendants Charles A. Heimbold ("Heimbold"), Peter R. Dolan ("Dolan") and Peter S. Ringrose ("Ringrose") (collectively, "Defendants"), have moved for this relief. Although Defendants fashion their motion as one seeking to strike Dr. Benumof's report and testimony in its entirety, in fact significant portions of his expert opinions are uncontested. In light of his qualifications and expertise, and Defendants' limited attack on his testimony, Dr. Benumof should not be precluded from testifying in this action.

Dr. Benumof is a prominent anesthesiologist in the United States who has submitted an expert report in this matter on issues relating to airway management. His report and testimony at his deposition: (1) explain particular medical terms involving airway management and angioedema; (2) explain the four cases of severe airway compromise that occurred in the initial Vanlev clinical trials that required intubation, cricothyrotomy and tracheotomy; (3) consider

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[1] Lead Plaintiff's expert reports were submitted as exhibits 12-19 to the Declaration of James W. Johnson, Esq. in Opposition to Defendants' Motion for Summary Judgment, dated February 4, 2005. To the extent any exhibits cited herein were submitted in support of or opposition to Defendants' summary judgment motion, they will be referred to as either "PX" or "DX" and will bear their original summary judgment reference number. Any new exhibits, which were not submitted either in support of or opposition to Defendants' summary judgment motion, are being submitted herewith as exhibits to the Declaration of James W. Johnson In Opposition to Defendants' Motions To Strike The Expert Testimony of Lead Plaintiff's Expert Witnesses, dated May 23, 2005 ("Johnson Opp. Decl."), and are referred to as "Pl. Opp. Ex. ___."

References to exhibits attached to the Declaration of Elissa Meth in Support of the Motions to Strike the Testimony of Michael J. Barclay, Jonathan L. Benumof, Allan S. Detsky, Robert C. Nelson, Paul D. Stolley, Frank C. Torchio and Robert H. Uhl, dated May 13, 2005, will be referred to as ("Meth Ex.").

BMS documents discussing, and purportedly disclosing, these four events to FDA and Vanlev clinical investigators prior to the New Drug Application ("NDA") submission to the United States Food and Drug Administration ("FDA"); (4) consider alleged disclosures about the four cases at major medical conferences in November 1999 and March 2000; and (5) identify and describe ten additional cases of significant upper airway narrowing that occurred during the initial Vanlev clinical trials.

Defendants largely concede that Dr. Benumof is qualified to and does render reliable opinions concerning the meaning of the airway terminology at issue in this action, particularly with respect to what the public would understand. Indeed, Defendants own experts have sought out Dr. Benumof's opinions in their own professional work on airway management courses. See Point II.A., infra. They also do not challenge Dr. Benumof's opinion regarding the medical terminology discussed in his report. (PX 13, Point II.) Finally, they do not dispute his identification or analysis of the ten additional cases of significant upper airway narrowing that occurred during the initial Vanlev clinical trials. (PX 13, Point VI.B.)

ARGUMENT

I. Legal Standards Governing Admission Of Expert Testimony

Rule 702 of the Federal Rules of Evidence govern the admissibility of expert testimony and provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. The rule was amended in 2000 in response to Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993), and to the many cases applying Daubert, including Kumho Tire Co. v. Carmichael, 526 U.S. 137 (1999), and General Elec. Co. v. Joiner, 522 U.S. 136, 140 (1997). More recently, in Schneider v. Fried, 320 F.3d 396, 405 (3d Cir. 2003), the Third Circuit described these requirements as the "trilogy of restrictions on expert testimony: qualification, reliability and fit."

Here, Dr. Benumof's report and testimony meet these standards. He should not be precluded from testifying in this action because he is eminently qualified and does possess sufficient knowledge, skill, experience, training or education in the field of anesthesiology and airway management, and is therefore competent to testify to the matters set forth in his report and testimony under Fed. R. Evid. 702. His opinion is reliable, given that it is based on decades of experience and training and extensive knowledge of the fields at issue and has a reasoned factual basis. The challenged testimony does not invade the province of the jury and would "assist the trier of fact to understand the evidence or to determine a fact in issue" as required by Rule 702. None of the testimony is repetitive of documentary evidence; therefore it should be admitted. Finally, any challenges under Rule 403 are premature.

II. Dr. Benumof Is Eminently Qualified to Opine on the Matters Set Forth in His Expert Report and Testimony

A. Dr. Benumof's Qualifications

Dr. Benumof is one of the most prominent anesthesiologists and airway management experts in the country. Even Defendants' experts acknowledge this and have sought out his experience and knowledge in their own professional work. See, e.g., Letter from Dr. Walls to Dr. Benumof, dated July 20, 1998 (Pl. Ex. Opp. Ex. 23); PX 39 163:23-167:16; Pl. Ex. 8 153:17-156:13. In 1998, Dr. Benumof assisted Drs. Walls and Murphy with their airway management

manual and course. In a letter of thanks, Dr. Walls wrote, "I do not know where to begin to thank you for your extensive, insightful, and extremely helpful edit of our manual. . . . I will be incorporating the majority of your suggestions into the manual and even where not directly incorporated, your suggestions have lead to additional critical thinking." (Pl. Ex. Opp. 23.)

Dr. Benumof received a Bachelor of Science degree from City College of the City University of New York in 1963 and his Medical Degree from the University of Southern in 1967. He also interned at the Los Angeles County, U.S.C. Medical Center from l967 to l968 and did his residency in the Department of Anesthesia, Columbia-Presbyterian Medical Center from l970 to l972. He was Chief of the Anesthesia Department for the l8th Surgical Hospital in Vietnam from l968 to l969 and Chief of the Anesthesia Department at Fort Rucker Army Hospital in Alabama from l969 to l970. Since 1973, he has been a professor of anesthesia at the University of California, School of Medicine, at San Diego ("U.C.S.D.") starting as an assistant professor and becoming a full-professor in 1982. He has been a visiting professor at numerous institutions. (PX 13, Ex. B at 14-16.) He is certified by the American Board of Anesthesiology. (Id. at 3.)

Dr. Benumof has received numerous awards within his field for his work, teaching and scholarship. (Id. at 3-7.) He is a member, and part of the administration of, many medical associations and societies, including the American Society of Anesthesiologists, the American Medical Association and the Society for Airway Management. (Id. at 7-8.) He has provided editorial services to several publications, including Anesthesiology and Journal of Cardiothoracic Anesthesia, and is a regular or occasional reviewer for 15 publications, including Chest, Circulation and JAMA. (Id. at 11-12.)

Dr. Benumof has personally presented or authored abstracts concerning anesthesia and airway management issues presented at major science meetings. (Id. at 17-19; Meth Ex. 2 33:12-34:10.) He has been invited to give lectures concerning anesthesia and airway management issues at approximately 300 major medical meetings. (Id. at 20-53.) He has published approximately 120 abstracts and authored or edited ten books, many of which have been translated and published in different languages concerning a wide range of anesthesia and airway management issues. (Id. at 54-67.) He has also written approximately 66 book chapters concerning anesthesia and airway management issues. (Id. at 74-80.) Dr. Benumof has had numerous medical intelligence articles, editorials, reviews, case reports, letters-to-the-editor and articles published on a wide range of anesthesia and airway management issues, including clinical and laboratory research within these fields. (Id. at 81-104, 109-115.) In addition to teaching at U.C.S.D., Dr. Benumof teaches courses on airway management and anesthesia to practitioners. (Id. at 87-89, 116.)

As testified to at his deposition, there is considerable interplay between the fields of cardiology and anesthesiology within the context of treating patients and Dr. Benumof's professional experience has provided him with expertise in cardiology. "[Cardiology] is a big part of doing anesthesia. You have to take care of the heart. So you have to understand cardiac physiology, cardiac pharmacology, every day, in every patient." (Meth Ex. 2 22:9-23:2.) He has served on committees concerned principally with cardiology. (Meth Ex. 2 27:19-28:4.) He has personally presented at a major meeting or been a senior author of a scientific abstract relating to cardiology. (Meth Ex. 2 31:24-32:24, 33:12-19.) Dr. Benumof has given invited lectures at a major medical meeting relating to cardiology. (Meth Ex. 2 35:9-36:17.) He has authored abstracts where cardiology, cardiovascular disease, hypertension, and heart failure were

an important concern. (Meth Ex. 2 38:24-41:8.) He has authored book chapters, editorials, reviews case reports, and letters-to-the-editor where cardiology is an important concern. (Meth Ex. 2 42:11-25, 45:6-9, 45:23-46:20, 49:11-17, 51:21-24.) He has performed clinical research where cardiology was an important concern. (Meth Ex. 2 47:25-4.) Cardiology has also been an important concern within the scope of his teaching. (Meth Ex. 2 53:9-54:11; 75:11-16.)

Dr. Benumof's experience is not limited to teaching or the operating room. As discussed at his deposition, Dr. Benumof regularly treats patients at U.C.S.D. and is called to respond to airway emergencies throughout the hospital; many new patients in an emergent situation are brought directly to the operating room at the U.C.S.D. Medical Center. (Meth Ex. 2 24:23-16, 72:3-74:25.) He also has gained expertise in the treatment of angioedema from the perspective of airway management: "Managing the airway of patients who have angioedema. In my hospital anesthesiologists would be the primary people to deal with it." (Meth Ex. 2 24:6-22; 187:18-190:25.)

Dr. Benumof is qualified to perform cricothyrotomies and tracheotomies, surgical procedures to secure the airway. (PX 13 at 3.) As he explained at this deposition, he is one of the principal promoters of needle cricothyrotomy, which uses a needle rather than a scalpel. (Meth Ex. 2 191:21-192:12.) While he has never performed a tracheotomy or scalpel cricothyrotomy on a human, he has expertise in both procedures and they are options that he considers and has ordered for a patient, although they would be performed by a surgeon. (Meth Ex. 2 192:13-194:10; Pl. Opp. Ex. 2 at 2.) Neither of Defendants' airway management experts have performed tracheotomies. (DX 25 196:12-15; DX 20 24:2-9.)

Dr. Benumof is highly sought out as an expert because of his knowledge and expertise. (Meth Ex. 2 56:23-57:9.) It is a small part of his professional life and in no way undermines his

credibility in this action, which is a matter for the jury to decide regardless. (Meth Ex. 2 57:10-12, 58:10-23.) It is not clear how Defendants determined that he has been an expert witness 600 times, given that he testified he has been a witness approximately 400 times.[2] (Meth Ex. 2 56:9-14.) He has testified at trial in approximately 60 to 80 cases. (Meth Ex. 2 7:6-14.)

B. Dr. Benumof Is Qualified Pursuant to Third Circuit Law on Expert Qualification

The Third Circuit has interpreted the specialized knowledge requirement more liberally than Defendants in moving to strike and preclude Dr. Benumof's testimony. In Elcock v. Kmart Corp., 233 F.3d 734 (3d Cir. 2000), the Third Circuit re-affirmed the standard for qualifying:

> Rule 702 requires the witness to have "specialized knowledge" regarding the area of testimony. The basis of this specialized knowledge "can be practical experience as well as academic training and credentials." We have interpreted the specialized knowledge requirement liberally, and have stated that this policy of liberal admissibility of expert testimony "extends to the substantive as well as the formal qualification of experts."

Id. at 741 (citations omitted) (emphasis added). In Holbrook v. Lykes Bros. Steamship Co., 80 F.3d 777, 782 (3d Cir.1996), the Third Circuit reversed the district court's exclusion of the plaintiff's treating physician's diagnosis of mesothelioma; the district court having excluded the testimony on the grounds that the physician was not a "pathologist, oncologist or expert in 'definitive cancer diagnosis'." The Third Circuit stated that the district court had construed the qualifications requirement too narrowly, and that the issue was ripe for exploration on cross-examination but not for Daubert exclusion, holding that:

> [b]ecause of our liberal approach to admitting expert testimony, most arguments about an expert's qualifications relate more to the weight to be given the expert's testimony than to its admissibility. Thus, witnesses may be competent to testify as experts even though they may not, in the court's eyes, be the 'best' qualified.

[2] Dr. Benumof estimated that he has been an expert for the defense in approximately 80% of the time. (Meth Ex. 2 5:16-23.)

> Who is 'best' qualified is a matter of weight upon which reasonable jurors may disagree. . . .[I]nsistence on a certain kind of degree or background is inconsistent with our jurisprudence in this area. . . .[I]t is an abuse of discretion to exclude testimony simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate.

Id. at 782. See also Knight v. Otis Elevator Co., 596 F.2d 84, 88 (3d Cir. 1979) (Third Circuit was reluctant "to require highly particularized, sub-specialization on the part of experts."); Lillis v. Lehigh Valley Hosp., Inc., No. 97-3459, 1999 WL 718231, at *6 (E.D. Pa. Sept. 3, 1999)("It is not for us to require that proponents of expert testimony provide witnesses with the qualifications that match a perfect fit to the issues presented. In fact, it would have been an abuse of discretion to do so."), aff'd, 251 F.3d 154 (3d Cir. 2000).

Here, as explained above, Dr. Benumof is more than sufficiently qualified to opine and draw inferences from the use of airway management terminology whatever the context of the use of that terminology, whether it be in presentations at major medical conferences or documents submitted to the FDA. He is not being offered as a "mind reading" expert. Dr. Benumof does not purport to opine on whether documents submitted to the FDA and clinical investigators met regulatory requirements. (PX 13 at 14-15.) Instead, he gives opinions about the airway terminology used in those documents and draws inferences from that use. This is perfectly appropriate and within the realm of his expertise. For example, he states:

> Based upon my extensive academic experience and experience as a practitioner, I conclude that the terms "airway compromise" or "some airway compromise" or a phrase like "some airway compromise that required some form of special treatment or hospitalization" are in no way synonymous with, or necessarily entail, the invasive last resort rescue and risky procedures of intubation or surgical airway. Rather, they generally describe a broad spectrum of conditions where the conditions requiring intubation or tracheostomy are on the very far end of that spectrum. Accordingly, I have made the following assessments

> with respect to the instances in which BMS described the four cases of invasive emergency rescue therapies.

(PX 13 at 14-15.)

Secondly, a fundamental issue in this case is whether information about Vanlev was disclosed to the public, who also attended the medical conferences at issue--at BMS's invitation--and read media reports about the conferences. (See, e.g., Lead Plaintiff's Statement Pursuant to Local Rule 56.1 ("Rule 56.1") at ¶171-179, 199-202, 324-333.) Importantly, Defendants do not challenge Dr. Benumof's ability to opine on matters directed at the public. (Def. Mem. at 15.)

Defendants also do not explain why particularized expertise, such as in hypertension medical conference procedures,[3] is fundamental to the opinions expressed by Dr. Benumof and thus to admissibility. Any purported lack of expertise is a matter for cross-examination. Contrary to Defendants' argument that all cardiology and hypertension experts who have testified in this action disagree[4] with Dr. Benumof's conclusion that airway compromise does not sufficiently convey the severity of the angioedema experienced by the four patients in the initial Vanlev clinical trials, (Memorandum of Law in Support of Defendants' Motion to Strike the Expert Testimony of Jonathan L. Benumof, dated May 13, 2005, ("Def. Mem.") at 14), the majority of them agree that airway compromise denotes a range of symptoms, some of which can be very mild. For example, Dr. Richard Grimm testified that airway compromise does not necessarily mandate immediate treatment. (Meth Ex. 2 30:20-32:2; see also, PX 39 at 6:17-7:14, 10:8-11:21, 12:18-13:19.) Regardless, the fact that there may be disagreement among experts

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[3] In any event, Dr. Benumof's experience with similar conferences qualifies him on this issue. See Point II.A., supra.

[4] Defendants draw an incorrect conclusion, in this regard, from Dr. Benumof's testimony that he has no basis for disagreeing with hypertension experts "about issues pertaining to that field." (Def. Mem. at 14.) He did not state that "airway compromise" and other such terms are such "issues." (Meth Ex. 2 141:24-142:4.) Clearly, these are terms used to describe the airway, a subject squarely within his field and upon which he has clear opinions.

does not mean that certain opinions are inadmissible. Dr. Benumof certainly is as qualified to opine on these matters as Defendants' experts, neither of whom have FDA regulatory "expertise," are cardiologists, or have presented at conferences sponsored by the American Heart Association ("AHA") or American College of Cardiology ("ACC") or Association of Black Cardiologists ("ABC"). (DX 20, Ex. 1; Pl. Ex. 8 45:16-22; DX 25, Ex. 1; PX 39 121:23-122:11.)

III. Dr. Benumof's Testimony Is Reliable

The essential guidance learned from Daubert, Kumho Tire and Joiner is that an expert's testimony must be based upon sufficient facts and flow from the reliable application of sound reasoning or methods. Fed. R. Evid. 702. Here, Dr. Benumof's testimony is reliable.

Nothing in Fed. R. Evid. 702 "suggests that experience alone—or experience in conjunction with other knowledge, skill, training or education—may not provide a reliable basis for expert testimony. To the contrary, the text of Rule 702 expressly contemplates that an expert may be qualified on the basis of experience." Fed. R. Evid. 702 Advisory Committee Notes; see also Kumho Tire, 526 U.S. at 156 (stating that "no one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience").

> The factors mentioned in Daubert . . .are not a hard test but rather a flexible inquiry into the overall reliability of a proffered expert's methodology. Therefore, we have 'considerable leeway' in deciding in each case 'how to go about determining whether particular expert testimony is reliable.' As the Third Circuit has suggested, the standard of reliability is not a high one. The main goal is to exclude so-called 'junk science' and ensure that expert testimony is based on sound methods and valid procedures.

Lehigh Valley Hospital, Inc., 1999 WL 718231, at *6 (expert appropriately testified about protocols, policies and procedures of defendant hospital despite qualification and reliability challenges). See also Schneider, 320 F.3d at 406 ("we note that expert testimony does not have to obtain general acceptance or be subject to peer review to be admitted under Rule 702."

"Where there are other factors that demonstrate the reliability of the expert's methodology, an expert opinion should not be excluded simply because there is no literature on point.")

A. Dr. Benumof's Inferences From Language Used by Defendants Are Reliable and Admissible

Dr. Benumof is not being offered as an expert on Defendants' minds. Instead, he is an expert in anesthesia and airway management, and his opinions are offered to interpret certain terminology used by Defendants. The fact that he may draws certain learned well-informed inferences from Defendants' use of specialized terms is not per se unreliable or inadmissible. See, e.g., 4 J. Weinstein & M. Berger, Weinstein's Federal Evidence, § 704.06[2][d], at 704-22.2 (2d ed. 2005) (even Rule 704(b) "does not prohibit expert testimony on surrounding circumstances from which a jury might infer mental state of the defendant. . . . Experts may testify about the meaning of circumstances surrounding an [act] in order to help the jury in determining whether the defendant has the requisite intent or other mental state. . . .")

B. Dr. Benumof's Conclusions Regarding Use of Terminology in Documents Directed to FDA and Clinical Investigators Are Reliable and Admissible

Defendants do not dispute or challenge the reliability of Dr. Benumof's opinions[5] about the meaning of the terminology used in any documents directed to the FDA or clinical investigators. Instead, they dispute his conclusion that the FDA and investigators[6] were misled in certain specific communications on the basis that he did not review "all of BMS's

[5] Dr. Benumof's general conclusion is, "Based upon my extensive academic experience and experience as a practitioner, I conclude that the terms "airway compromise" or "some airway compromise" or a phrase like "some airway compromise that required some form of special treatment or hospitalization" are in no way synonymous with, or necessarily entail, the invasive last resort rescue and risky procedures of intubation or surgical airway. Rather, they generally describe a broad spectrum of conditions where the conditions requiring intubation or tracheostomy are on the very far end of that spectrum." (PX 13 at 14.)

[6] However, the sole focus of Defendants' argument is the FDA. (Def. Mem. at 10-13.)

communications with the FDA, or even all of BMS's significant communications with the FDA" and that the documents he reviewed were improperly selected and limited by counsel. This argument has absolutely no merit.

First, Defendants have not justified or even explained why Dr. Benumof must have reviewed all of Defendants' communications with FDA to render opinions about certain specified documents. (PX 13 at 14-15.)

Second, Dr. Benumof's opinion with respect to communications with the FDA is, as Defendants well know, limited to the period before the NDA was submitted; thus Defendants have not identified a single[7] document before that submission to counter his opinion. (See, e.g., PX 13 at 15, 20 (noting that BMS's March 31, 2000 supplement appropriately used the words "intubation" and "tracheotomy"); Meth Ex. 2 230:2-9.)

Third, Drs. Walls and Murphy reviewed the same documents reviewed by Dr. Benumof in rendering his opinions, plus the irrelevant post-NDA filing documents mentioned by Defendants. (DX 25 ¶10; 20 ¶10; see, e.g., PX 39 136:3-15.)

Fourth, Dr. Benumof reviewed a reliable set of relevant documents, which included: clinical, medical and other records concerning the four cases of life-threatening angioedema that required intubation or surgical airway; internal BMS correspondence regarding the four cases; documents for submission to FDA and clinical investigators; public presentations regarding

[7] Likely, in reply, Defendants will mention that BMS's former Investor Relations Vice-President, Timothy Cost, has testified that he used the word "intubation" publicly with analysts. He is the only witness in this action to so testify. He does not use the word intubation during the analyst conference call related to the AHA conference. (DX 53.) Mr. Cost's testimony should have no bearing on whether the communications reviewed by Dr. Benumof were misleading, but clearly that is a matter for the tier of fact to decide. In any event, Dr. Benumof's opinions are clear, the terms "intubation," "tracheotomy" or "cricothyrotomy" should have been used to disclose the severity of the situations faced by the four patients. It is when the term is not used that communications are misleading.

Vanlev from the AHA and ACC/ABC medical conferences; material relating to the AHA and ACC medical conferences (including a transcript of Dr. Weber's presentation at AHA)[8] ; and unedited deposition transcripts for the medical conference presenters (Drs. Weber, Pouleur and Black) and other key BMS employees). (PX 13, Ex. B.)

The above notwithstanding, any contention that Dr. Benumof did not review all relevant documents should go to the weight of his testimony, not admissibility, in light of the fact that he reviewed a reliable grouping of relevant documents. Taylor v. Danek Medical, Inc., No. 95-7232, 1999 WL 310647, at *2 (E.D. Pa. May 10, 1999) ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are traditional and appropriate means of attacking shaky but admissible evidence.") Accordingly, Dr. Benumof's testimony should be admitted.

Lastly, Defendants intimate that Dr. Benumof reached these opinions before receiving any documents. Defendants misconstrue his testimony and appear to have forgotten that Dr. Benumof submitted a certification in 2000 in opposition to their first motion to dismiss, after having reviewed their papers contending that the intubations had been disclosed. (Meth Ex. 2 94:23-96:4, 97:2-5.) He did not impermissibly form any of his opinions prematurely or at counsel's urging. (Meth Ex. 2 81:2-5; 97:15-98:3.)

C. Dr. Benumof's Conclusions Regarding Use of Terminology in Statements Made at Medical Conferences Are Reliable and Admissible

Again Defendants do not appear to dispute or challenge the reliability of Dr. Benumof's opinions about the meaning of the terminology used at any of the medical conferences. Instead

[8] A transcript of the presentations at the ACC/ABC conference was not produced by Defendants.

they take his opinions out of context to argue that he is proffering expert testimony on mind-reading and that he improperly relied on "a single box" of documents. (Def. Mem. at 13.)

Dr. Benumof is not being offered as an expert on whether the conference attendees were actually mislead.[9] He is appropriately opining on whether certain specialized terminology used at the conferences connoted the seriousness of the four intubation events or whether it was misleading. (PX 13 16-17.) To the extent he draws certain learned well-informed inferences, such as what a generic reasonable physician or person would know, from Defendants' use of specialized terms in the presentations, that is not per se unreliable or inadmissible. See 4 Weinstein's Federal Evidence, § 704.06[2][d], at 704-22.2 ("Experts may testify about the meaning of circumstances surrounding an [act] in order to help the jury in determining whether the defendant has the requisite intent or other mental state. . . .")

With respect to the set of documents that Dr. Benumof reviewed, as discussed above, Defendants have not identified a single document to counter his opinions in this regard. Second, Drs. Walls and Murphy reviewed the same documents reviewed by Dr. Benumof in critiquing his opinions and opining that physicians would not have been misled. (DX 25 ¶10; 20 ¶10.) Third, Dr. Benumof reviewed a reliable set of relevant documents, which included: clinical, medical and other records concerning the four cases of life-threatening angioedema that required intubation or surgical airway; internal BMS correspondence regarding the four cases; documents for submission to FDA and clinical investigators; public presentations regarding Vanlev from the AHA and ACC/ABC medical conferences; material relating to the AHA and ACC medical

[9] To the extent any of Dr. Benumof's opinions read this way, because of introductory language, they could be cured by instruction or redaction.

conferences (including a transcript of Dr. Weber's presentation at AHA);[10] and unedited deposition transcripts for the medical conference presenters (Drs. Weber Pouleur, and Black) and other key BMS employees). (PX 13, Ex. B.) The above notwithstanding, any contention that Dr. Benumof did not review all relevant documents should go to the weight of his testimony, not its admissibility.

To the extent Defendants are arguing that Dr. Benumof has offered no reliable basis for concluding that the terminology used was misleading, they are wrong and misapply Daubert. Dr. Benumof is offering more than his "common sense." His opinions are based on 35 years of academic and professional knowledge, experience and expertise.[11] As explained in his report and at his deposition, airway narrowing or "compromise," as used by Defendants, occurs on a curve (of the Pouseille relationship) that goes from essentially no life-threat to complete closure and life-threat. (PX 13 at 19 (citing L. Benumof, M.D., Anesthesia for Thoracic Surgery, at 66-67 (2d ed. 1995)); Meth Ex. 2 103:21-114-8; Pl. Opp. Ex. 2; Pl. Opp. Ex. 21.) Thus, using the phrase "airway compromise" to connote only one end of this range is misleading, particularly given the treatments used with the four patients in the initial Vanlev clinical trials. (PX 13 at 2-4, 14, 15, 19; Meth Ex. 2 103:21-114-8, 145:3-146:2.)

As Dr. Benumof testified with respect to the opinions of Drs. Murphy and Walls:

> I think they failed to take into consideration and directly address the basis for my opinion. I think that the basic pathophysiology, as I described to you in Exhibit A and Exhibit B, is the very fundamental laws of physiology, of not even physics. It's

[10] A transcript of the presentations at the ACC/ABC conference was not produced by Defendants.

[11] See, e.g., Tormenia v. First Investors Realty Co., 251 F.3d 128, 135 (3d Cir. 2000), where the Third Circuit rejected the notion that an expert's opinions "were purely personal in nature and consequently devoid of any underlying methodology" where the expert's testimony was derived from a combination of general principles of physical science with his own experience applied to the questions at issue.

> incontrovertible. This is the way airway narrowing behaves. This is the pathophysiology of it. It is a spectrum. It goes from zero to infinity. That has implications for the way patients present in terms of signs and symptoms, the way they get treated, the time available to treat them, and the options that are available within that time.

(Meth Ex. 2 145:3-24.)

Dr. Benumof has provided a sufficient basis for his opinion; in fact, few witnesses in this action disagree that airway compromise denotes a range of conditions. They clearly disagree about the import of this fact, but that does not make Dr. Benumof's opinions inadmissible under Daubert.

D. Dr. Benumof Can Properly Testify at Trial Regarding the Manner in Which Intubation, Cricothyrotomy and Tracheotomy Are Performed

Dr. Benumof sufficiently describes the procedures of intubation, cricothyrotomy and tracheotomy in his report to lay the foundation for a proffer of a demonstration of these procedures. (PX 13 at 3.) It is also the case that he has the knowledge and expertise to demonstrate these procedures if he is asked to do so. See Point II.A., supra.

IV. Dr. Benumof's Testimony Meets the "Fit" Requirement And Should Be Admitted

In addition to reliability, Rule 702 requires that the expert's testimony must assist the trier of fact in its determination of the claims and defenses. "This standard is not intended to be a high one." Oddi v. Ford Motor Co., 234 F.3d 136, 145 (3d Cir. 2000). "Under Rule 702, moreover, expert testimony is more broadly admissible than it was under the common law. Thus, expert testimony is admissible if it will simply assist the trier of fact to understand the facts already in the record, even it all it does is put those facts in context." 4 Weinstein's Federal Evidence, § 702.03[1], at 702-34.

Contrary to Defendants' assertions, Dr. Benumof's testimony clearly fits the facts of this case, would assist the trier of fact, and not usurp its function.

A. Dr. Benumof's Inferences From Language Used by Defendants Are Admissible and Do Not Invade the Province of the Jury

Rule 704 of the Federal Rules of Evidence indicates that Dr. Benumof's opinions concerning inferences about Defendants' actions are not per se inadmissible because they may "embrace an ultimate issue to be decided by the trier of fact." (Def. Mem. at 7.) For example, even Rule 704(b) "does not prohibit expert testimony on surrounding circumstances from which a jury might infer mental state of the defendant. . . . Experts may testify about the meaning of circumstances surrounding an [act] in order to help the jury in determining whether the defendant has the requisite intent or other mental state. . . ." 4 Weinstein's Federal Evidence, § 704.06[2][d], at 704-22.2; see also Crowley v. Chait, 322 F. Supp. 2d 530, 550 (D.N.J. 2004) (court refused to exclude expert report on Daubert grounds, "because he made occasional use of the word 'negligent' or the phrase 'should have known.'")

Dr. Benumof's opinions focus on the meaning of the specialized terminology used by Defendants and his testimony would assist the jury, not usurp its function.

B. Dr. Benumof's Conclusions Regarding Use of Terminology in Documents Directed to FDA and Vanlev Clinical Investigators Are Admissible and Fit

Dr. Benumof's conclusions regarding the use of terminology in documents directed at FDA and Vanlev clinical investigators are relevant and probative of whether Defendants' acted intentionally or recklessly with respect to their efforts to disclose the four cases of intubation and tracheotomy. (Def. Mem. at 12-13.)

In a securities case, a plaintiff can show conscious misbehavior by adducing facts that defendants had actual knowledge that their statements were false or misleading at the time they

were made. GSC Partners CDO Fund v. Washington, 368 F.3d 228, 238-39 (3d Cir. 2004). Recklessness can be shown by establishing "defendants' knowledge of facts or access to information contradicting their public statements." Novak v. Kasaks, 216 F.3d 300, 308 (2d Cir. 2000); In re Nice Sys., Ltd. Sec. Litig., 135 F. Supp. 2d 551, 585 (D.N.J. 2001) (same). A reckless statement is "a material misrepresentation or omission involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." GSC Partners, 368 F.3d at 239. "An egregious refusal to see the obvious, or investigate the doubtful, may in some cases give rise to an inference of recklessness." In re Nice Sys., 135 F. Supp. 2d at 585. Dr. Benumof's opinions concerning alleged failures to disclose the four events in any BMS communication would assist a jury in determining Defendants' intentional or recklessness conduct.

In addition to being probative, the documents reviewed by Dr. Benumof use specialized terminology, specifically "airway compromise" and "intervention," which requires the assistance of an expert.

C. Dr. Benumof's Conclusions Regarding Use of Terminology in Statements Made at Medical Conferences Are Admissible

Oddly, Defendants' argue that Dr. Benumof's opinions regarding whether the statements made at the AHA and ACC/ABC medical conferences were misleading "do not fit the issues in dispute." (Def. Mem. at 17.) To come to this conclusion, they misconstrue and circumscribe Dr. Benumof's opinions. His "central conclusions" are that the terminology used by Defendants are not synonymous with intubation or tracheotomy (as is posited by Defendants' Dr. Murphy and has been argued by Defendants, particularly in their first motion to dismiss this action), that the terminology does not convey the import of the procedures used to save the lives of these four

patients, and that the terminology does not convey the life-threatening nature of the four events and the severity of the angioedema caused by Vanlev.

As Dr. Benumof states in the conclusion of his report:

> Overall, it is very clear to me that it was grossly misleading and minimized the seriousness of the actual events cause[d] by Vanlev whenever and wherever BMS used the term "airway compromise" or "angioedema" to describe airway narrowing so serious as to require the emergency invasive life-saving rescue therapies of "intubation" or "tracheostomy."

(PX 13 at 24.) Put another way, Dr. Benumof repeatedly concludes that the term "airway compromise" does not "indicate a life-threatening condition requiring immediate treatment." (PX 13 at 17; Meth Ex. 2 103:12-24.)

Clearly, these matters are at the heart of the claims against Defendants.

D. Dr. Benumof Can Properly Testify at Trial Regarding the Manner in Which Intubation, Cricothyrotomy and Tracheotomy Are Performed

To the extent Defendants are raising a Rule 403 challenge to a proffer of a demonstration of the manner in which intubation, cricothyrotomy and tracheotomy is done, it is premature and inappropriate within the context of their Daubert motion and should be disregarded by the Court.

In In re Paoli R.R.Yard PCB Litig., 35 F.3d 717 (3d Cir. 1994) ("Paoli II"), the Third Circuit explained that when balancing the reliability of expert testimony against the possibility that admitting the evidence would overwhelm, confuse or mislead the jury, there is a presumption of helpfulness. Paoli II, 35 F.3d 746. The court also said that the extent to which an adverse party has had notice and the opportunity to present his or her own experts is also relevant. The court reiterated its opinion that in order for a district court to exclude scientific evidence, there must be something particularly confusing about the scientific evidence at issue. The Paoli II court also noted that the fact that Daubert held that Rule 702 is the primary locus of

a court's gatekeeping role indicates that exclusion under Rule 403 should be rare. Paoli II, 35 F.3d at 747 fn. 16. Finally, the Paoli II court noted that " Rule 403 is rarely appropriate as a basis of pre-trial exclusion, because a judge cannot ascertain potential relevance until that judge has a virtual surrogate for a trial record." Paoli II, 35 F.3d at 747.

In In re Paoli R.R.Yard PCB Litig., 916 F.2d 829 (3d Cir. 1990) ("Paoli I"), the Court said in the context of considering motions to exclude experts' testimony under Rule 403: "Moreover we stress that pretrial Rule 403 exclusions should rarely be granted. . . .'If . . . testimony survives the rigors of Rule 702 and 703. . .Rule 403 is an unlikely basis for exclusion.' Excluding evidence as being more prejudicial than probative at the pretrial stage is an extreme measure that is rarely necessary, because no harm is done by admitting it at that stage." Paoli I, 916 F.2d at 859 (internal citations omitted). Accordingly, Defendants' motion to exclude Dr. Benumof's proffered testimony regarding the procedures of intubation, tracheotomy or cricothyrotomy at this stage should be denied.

E. None of Dr. Benumof's Testimony Should Be Excluded Because It Is Repetitive of Documentary Evidence

Each of Dr. Benumof's opinions interpreting the terminology used in the various documents and deposition testimony discussed in his report is admissible. "Under Rule 702. . . expert testimony is more broadly admissible than it was under the common law. Thus, expert testimony is admissible if it will simply assist the trier of fact to understand the facts already in the record, even it all it does is put those facts in context." 4 Weinstein's Federal Evidence, § 702.03[1], at 702-34. This is particularly true within the Third Circuit where "doubts about whether an expert's testimony will be usefully should generally be resolved in favor of admissibility." Id. at §702.03[3] at 702-43. Weinstein also notes that experts such as Dr. Benumof "with skill or expertise in a particular industry may testify to the meaning of . . . terms

that have specialized meaning in that industry, because evidence of those specialized meanings will assist the jury in interpreting the [document]." Id. at §702.03[3] at 702-43.

CONCLUSION

For the reasons set forth above, Lead Plaintiff respectfully requests that the Court deny Defendants' motion to strike the testimony of Dr. Benumof. At a minimum, the portions of his report that have not been challenged are admissible given that Dr. Benumof has been shown to be qualified, his opinions are reliable and they "fit" the issues in this case.

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